

reports detailing compliance with the order.

The purpose of this analysis is to facilitate public comment on the proposed order, and it is not intended to constitute an official interpretation of the agreement and proposed order, or to modify any of their terms.

Donald S. Clark,

Secretary.

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[File No. 943-3277]

Johnson & Johnson Consumer Products Inc.; Consent Agreement With Analysis To Aid Public Comment

AGENCY: Federal Trade Commission.

ACTION: Consent agreement.

SUMMARY: In settlement of alleged violations of federal law prohibiting unfair acts and practices and unfair methods of competition, this consent agreement, accepted subject to final Commission approval, would, among other things, prohibit a New Jersey-based consumer products company and its parents corporation (1) from representing, in any manner, directly or by implication, the efficacy of any over-the-counter product—as a contraceptive or as a method of protection against the transmission of any sexually-transmitted disease—unless, at the time of making any such representation, the companies possess and rely upon competent and reliable scientific evidence that substantiates such representation; and (2) from misrepresenting in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study relating to any over-the-counter product with a use relating to human reproduction, reproductive organs or sexually-transmitted diseases.

DATES: Comments must be received on or before December 26, 1995.

ADDRESSES: Comments should be directed to: FTC/Office of the Secretary, Room 159, 6th Street and Pennsylvania Avenue, NW, Washington, DC. 20580.

FOR FURTHER INFORMATION CONTACT: Linda K. Badger, San Francisco Regional Office, 901 Market Street, Suite 570, San Francisco, California 94103. (415) 356-5270.

SUPPLEMENTARY INFORMATION: Pursuant to Section 6(f) of the Federal Trade Commission Act, 38 Stat. 721, 15 U.S.C. 46, and Section 2.34 of the Commission's Rules of Practice (16 CFR 2.34), notice is hereby given that the following consent agreement containing

a consent order to cease and desist, having been filed with and accepted, subject to final approval, by the Commission, has been placed on the public record for a period of sixty (60) days. Public comment is invited. Such comments or views will be considered by the Commission and will be available for inspection and copying at its principal office in accordance with Section 4.9(b)(6)(ii) of the Commission's Rules of Practice (16 CFR 4.9(b)(6)(ii)).

The Federal Trade Commission having initiated an investigation of certain acts and practices of Johnson & Johnson Consumer Products, Inc., a corporation, and it now appearing that the proposed respondent and its parent corporation, Johnson & Johnson, are willing to enter into an agreement containing an order to cease and desist from the use of the acts and practices being investigated,

It is hereby agreed by and between Johnson & Johnson Consumer Products, Inc., a corporation, by its duly authorized officer, and its attorney, and its parent corporation, Johnson & Johnson, and its duly authorized officer, and its attorney, and counsel for the Federal Trade Commission that:

1. Proposed respondent Johnson & Johnson Consumer Products, Inc., is a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey, with its office and principal place of business located at 1999 Grandview Road, Skillman, New Jersey 08588.

Johnson & Johnson is a corporation organized, existing and doing business under and by virtue of the laws of the State of New Jersey, with its office and principal place of business located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

2. Proposed respondent and its parent corporation admit all the jurisdictional facts set forth in the draft of complaint.

3. Proposed respondent and its parent corporation waive:

- a. Any further procedural steps;
- b. The requirement that the Commission's decision contain a statement of findings of fact and conclusions of law;
- c. All rights to seek judicial review or otherwise to challenge or contest the validity of the order entered pursuant to this agreement; and
- d. Any claim under the Equal Access to Justice Act.

4. This agreement shall not become part of the public record of the proceeding unless and until it is accepted by the Commission. If this agreement is accepted by the Commission, it, together with the draft of complaint contemplated thereby, will

be placed on the public record for a period of sixty (60) days and information in respect thereto publicly released. The Commission thereafter may either withdraw its acceptance of this agreement and so notify the proposed respondent and its parent corporation, in which event it will take such action as it may consider appropriate, or issue and serve its complaint (in such form as the circumstances may require) and decision, in disposition of the proceeding.

5. This agreement is for settlement purposes only and does not constitute an admission by the proposed respondent or its parent corporation of facts, other than jurisdictional facts, or of violations of law as alleged in the draft of complaint.

6. This agreement contemplates that, if it is accepted by the Commission, and if such acceptance is not subsequently withdrawn by the Commission pursuant to the provisions of Section 2.34 of the Commission's Rules, the Commission may, without further notice to the proposed respondent or its parent corporation, (a) issue its complaint corresponding in form and substance with the draft of complaint and its decision containing the following order to cease and desist in disposition of the proceeding and (b) make information public in respect thereto. When so entered, the order to cease and desist shall have the same force and effect and may be altered, modified or set aside in the same manner and within the same time provided by statute for other orders. The order shall become final upon service. Delivery by the U.S. Postal Service of the complaint and decision containing the agreed-to order to the proposed respondent's address and to its parent corporation's address as stated in this agreement shall constitute service. The proposed respondent and its parent corporation waive any right they may have to any other manner of service. The complaint may be used in construing the terms of the order, and no agreement, understanding, representation, or interpretation not contained in the order or the agreement may be used to vary or contradict the terms of the order.

7. The proposed respondent and its parent corporation have read the proposed complaint and order contemplated hereby. The proposed respondent and its parent corporation understand that once the order has been issued, they will be required to file one or more compliance reports showing that they have fully complied with the order. The proposed respondent and its parent corporation further understand

that they may be liable for civil penalties in the amount provided by law for each violation of the order after it becomes final.

Order

I

It is ordered that respondent, Johnson & Johnson Consumer Products, Inc., a corporation, its parent corporation, Johnson & Johnson, and all the other subsidiaries of Johnson & Johnson, their successors and assigns (hereinafter collectively "the companies"), and the companies' officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale or distribution of K-Y Plus Nonoxynol-9 Spermicidal Lubricant, or any other personal lubricant and/or spermicide, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication, relating to:

A. The failure rate of any method of contraception due to defects, misuse, or any other cause;

B. Any such product's ability to provide protection against the development of tiny holes in condoms during use;

C. Any such product's ability to provide protection against HIV and other viruses; or

D. The health-related benefits of any such product; unless, at the time of making any such representation, the companies possess and rely upon competent and reliable scientific evidence that substantiates such representation. For the purposes of this Order, "competent and reliable scientific evidence" shall mean those tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, that have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results.

II

It is further ordered that the companies and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale or distribution of any "food," "drug" or "device," as those terms are defined in Section 15 of the Federal

Trade Commission Act, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from representing, in any manner, directly or by implication, the efficacy of any over-the-counter product as a contraceptive or as a method of protection against the transmission of any sexually-transmitted disease, unless, at the time of making any such representation, the companies possess and rely upon competent and reliable scientific evidence that substantiates such representation.

III

It is further ordered that the companies and their officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the manufacturing, labelling, advertising, promotion, offering for sale, sale or distribution of any over-the-counter product with a use relating to human reproduction, reproductive organs or sexually-transmitted diseases, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from misrepresenting in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study.

IV

It is further ordered that for five (5) years after the last date of dissemination of any representation covered by this Order, the companies shall maintain and upon request make available to the Federal Trade Commission for inspection and copying:

A. All materials that were relied upon in disseminating such representation; and

B. All tests, reports, studies, surveys, demonstrations or other evidence in their possession or control that contradict, qualify, or call into question such representation, or the basis relied upon for such representation, including complaints from consumers.

V

It is further ordered that the companies notify the Commission at least thirty (30) days prior to any proposed change in the companies such as dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in the corporation which may affect compliance obligations arising out of the Order.

VI

It is further ordered (1) that respondent Johnson & Johnson Consumer Products, Inc., shall, within ten (10) days from the date of service of this Order upon it, distribute a copy of this Order to each of its operating divisions, to each of its managerial employees, and to each of its officers, agents, representatives or employees engaged in the preparation, review or placement of advertising or other materials covered by this Order, and (2) that the parent corporation, Johnson & Johnson, shall, within ten (10) days from the date of service of this Order upon it, distribute a copy of this Order to each of its and of its subsidiaries' officers, agents, representatives or employees engaged in the preparation, review of placement of advertising of any over-the-counter product with a use relating to human reproduction, reproductive organs or sexually-transmitted diseases.

VII

It is further ordered that this Order will terminate twenty years from the date of its issuance, or twenty years from the most recent date that the United States or the Federal Trade Commission files a complaint (with or without an accompanying consent decree) in federal court alleging any violation of the Order, whichever comes later; provided, however, that the filing of such complaint will not affect the duration of:

A. Any paragraph in this Order that terminates in less than twenty years;

B. This Order's application to any respondent that is not named as a defendant in such complaint; and

C. This Order if such complaint is filed after the Order has terminated pursuant to this paragraph.

Provided further, that if such complaint is dismissed or a federal court rules that the respondent did not violate any provision of the Order, and the dismissal or ruling is either not appealed or upheld on appeal, then the Order will terminate according to this paragraph as though the complaint was never filed, except that the Order will not terminate between the date such complaint is filed and the later of the deadline for appealing such dismissal or ruling and the date such dismissal or ruling is upheld on appeal.

VIII

It is further ordered that the companies shall, within sixty (60) days from the date of service of this Order upon them, and at such other times as the Commission may require, file with

the Commission a report, in writing, setting forth in detail in the manner and form in which they have complied with this Order.

IX

It is further ordered that nothing in this Order shall prohibit the companies from making any representation for any drug that is permitted in labeling for any such drug under any tentative final or final standard promulgated by the Food and Drug Administration, or under any new drug application approved by the Food and Drug Administration.

Analysis of Proposed Consent Order to Aid Public Comment

The Federal Trade Commission has accepted an agreement, subject to final approval, to a proposed consent order from respondent Johnson & Johnson Consumer Products, Inc. Its parent corporation, Johnson and Johnson, although not a respondent, also agreed to be bound by the terms of the consent order. Both parent and subsidiary are New Jersey corporations.

The proposed consent order has been placed on the public record for sixty (60) days for reception of comments by interested persons. Comments received during this period will become part of the public record. After sixty (60) days, the Commission will again review the agreement and the comments received and will decide whether it should withdraw from the agreement and take other appropriate action or make final the agreement's proposed order.

Johnson & Johnson Consumer Products, Inc., manufacturers and sells baby care products, personal care products for adults, and bandages. This matter concerns this company's "Condom Insurance" advertisements for its "K-Y Plus Brand Spermicidal Lubricant with NonOxynol-9" ("K-Y Plus"). In these advertisements, Johnson & Johnson CPI promote the use of K-Y Plus with condoms as "insurance" to protect against unwanted pregnancies, and HIV and other sexually transmitted diseases ("STDs") in case of condom failure. The ads warn consumers to use K-Y Plus because one in six condoms allegedly fails.

The Commission's complaint charges that respondent's advertising contained false and/or unsubstantiated representations regarding the failure rate of condoms and the effectiveness of K-Y Plus. Specifically, the complaint alleges that the respondent falsely represented that scientific tests or studies show that up to eighteen and one half percent of condoms will fail, leaving users vulnerable to pregnancy and sexually transmitted diseases. The

complaint also alleges that the respondent made unsubstantiated claims that: (1) One out of six condoms develops tiny holes during use which are big enough for sperm, HIV and other viruses to pass through; (2) one out of six condoms fails due to mistake in using condoms or through the development of tiny holes during use; (3) K-Y Plus provides protection against the development of tiny holes in condoms during use; and (4) K-Y Plus provides protection against HIV and other viruses.

The proposed consent order contains provisions designed to remedy the violations charged and to prevent the respondent or its parent corporation from engaging in similar acts and practices in the future. Part I of the proposed order would prohibit the companies from making any of the unsubstantiated claims delineated above, or any other claims of a health-related benefit, for K-Y Plus or any other spermicide and/or lubricant, unless at the time of making them, they possess and rely upon competent and reliable evidence, which when appropriate must be competent and reliable scientific evidence.

Part II of the proposed order includes fencing-in relief, prohibiting the companies from representing, in any manner, directly or by implication, the efficacy of any over-the-counter product as a contraceptive or as a method of protection against the transmission of any sexually-transmitted disease, unless, at the time of making any such representation, the companies possess and rely upon competent and reliable scientific evidence that substantiates such representation.

Part III of the proposed order prohibits the companies from misrepresenting in any manner, directly or by implication, the existence, contents, validity, results, conclusions, or interpretations of any test or study relating to any over-the-counter product with a use relating to human reproduction, reproductive organs or sexually-transmitted diseases.

The proposed order also requires the companies to maintain materials relied upon to substantiate claims covered by the order; to provide a copy of the consent agreement to all employees or representatives involved in the preparation and placement of the company's advertisements, as well as to all company executives and marketing and sales managers; to notify the Commission of any changes in corporate structure that might affect compliance with the order; and to file one or more reports detailing compliance with the order.

The purpose of this analysis is to facilitate public comment on the proposed order. It is not intended to constitute an official interpretation of the agreement and proposed order or to modify in any way their terms.

Donald S. Clark,
Secretary.

Concurring Statement of Commissioner Mary L. Azcuenaga in Johnson & Johnson Consumer Protects Inc. File No. 943 3277

In concur in the acceptance of the proposed consent agreement for public comment except to the extent that the proposed order imposes obligations on Johnson & Johnson (the parent company of the respondent Johnson & Johnson Consumer Products Inc.), which is not named in the accompanying complaint.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 95N-0344]

Drug Export; AVONEX™, Recombinant Interferon Beta-1a

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Biogen, Inc., has filed an application requesting approval for the export of the human biological product AVONEX™, Recombinant Interferon Beta-1a to the United Kingdom.

ADDRESSES: Relevant information on this application may be directed to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, and to the contact person identified below. Any future inquiries concerning the export of human biological products under the Drug Export Amendments Act of 1986 should also be directed to the contact person.

FOR FURTHER INFORMATION CONTACT: Cathy E. Conn, Center for Biologics Evaluation and Research (HFM-610), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-2006.

SUPPLEMENTARY INFORMATION: The drug export provisions in section 802 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 382) provide that FDA may approve applications for the